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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/879,146  | 06/12/2001  | Koon-Wah Leong       | LFS-114             | 5234             |
| 24353   | 7590        | 01/22/2004           | EXAMINER            |                  |
| BOZICEVIC, FIELD & FRANCIS LLP<br>200 MIDDLEFIELD RD<br>SUITE 200<br>MENLO PARK, CA 94025 |             |                      | OLSEN, KAJ K        |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1753                |                  |

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/879,146

Applicant(s)

LEONG ET AL.

Examiner

Kaj Olsen

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 31-35, 43-50 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-30, 36-42, 51, 54 and 55 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 52, 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6-12,6-04 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. In applicant's election, applicant neglected to elect one of electrochemical sensing or colorimetric analysis. The examiner contacted the applicant to point this out and the applicant indicated that they wish to elect electrochemical sensing. Claim 56 is withdrawn from further consideration. Hence all the claims withdrawn from further consideration are 31-35, 43-50 and 56.
2. Applicant indicated that they believe a search of all the inventions would not constitute an undue burden to the examiner. The examiner disagrees. Claims 31-35 are not drawn to a micro-needle or skin piercing device and a search of that in addition to piercing devices constitutes an undue burden on the examiner. Similarly, claims 43-50 are not even drawn to electrochemical structure and a search of that also constitutes an undue burden on the examiner.
3. The requirement is still deemed proper and is therefore made FINAL.

### *Double Patenting*

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1753

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2, 7-20, 36-42, and 51-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 9-39, 48, and 50-54 of copending Application having docket number Life-019 with or without the further teaching of Yukawa et al (USP 6,059,946).

6. In the IDS of 3-17-2003, applicant provided a series of claims for an application having the docket number Life-019. The applicant also listed application numbers associated with the provided disclosure. However, none of the listed application numbers appear to correspond with the claims of Life-019. In fact, one of the serial numbers listed (08/879,198) doesn't appear to have anything to do with the provided disclosure (neither did 09/879,198). The examiner requests the applicant's assistance in identifying what serial number is associated with this disclosure.

7. With respect to this rejection, the set forth subject matter of claims 1 and 19 of the instant invention overlap with the claimed subject matter of claims 1 and 21 of Life-019. The claims differ only that the claims of Life-019 set forth that the constituent transfer medium (i.e. fluid transfer medium) is hydrophilic. First claim 2 of the instant invention further limits the fluid transfer medium of claim 1 by specifying that it is hydrophilic material. In addition, Yukawa teaches that the material that delivers fluid to the electrodes of an electrochemical cell should be hydrophilic (col. 4, lines 33-51). Hydrophilic material facilitates the wicking of fluid to the electrode thereby improving signal to noise and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Yukawa for the

Art Unit: 1753

claimed instant invention in order to improve electrode access to the fluid to be analyzed. The various dependent claims of the instant invention closely overlap corresponding claims of Life-019.

8. This is a provisional obviousness-type double patenting rejection.

### *Claim Objections*

9. Claim 52 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from two claims simultaneously. Dependent claims are only permitted to depend from a plurality of claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 52 and 53 have not been further treated on the merits.

### *Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1753

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 5, 7-13, 15-18 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/64580 (hereafter "WO '580") in view of Mullen (USP 5,231,028).

13. WO '580 discloses a biological fluid sampling device that comprises at least one skin-piercing member comprising a biological fluid access opening. See pp. 19-21 as an example. WO '580 also discloses the presence of an electrochemical cell for measuring the analyte within the biological fluid. See p. 11, lines 4-11 and p. 25, line 23 through p. 26, line 10. WO '580 further discloses the use of a fluid transfer medium that assists in the transferring of fluid to the electrochemical cell. See p. 3, lines 28-31. WO '580 does not explicitly disclose the use of a porous electrode for the electrode of the electrochemical sensor. However, it is well known in the art of electrochemical sensing to utilize porous electrodes to increase the effective surface area of the electrodes. This is demonstrated by the teaching of Mullen where the use of porous electrodes is both acknowledged as being prior art and is improved upon providing a sensor with low sensitivity to alcohol as well as a faster response time and increased current densities (col. 1, line 34 through col. 2, line 58). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Mullen for the device of WO '580 in order to minimize interferent response, increase response times, and improved the current density for the sensor.

14. With respect to the presence of a second electrode, electrochemical measurements inherently require at least two electrodes. Finding the appropriate spacing between the electrodes requires only routine skill in the art.

Art Unit: 1753

15. With respect to a plurality of pores for the fluid transfer medium, membranes inherently possess a plurality of pores. Finding the appropriate pore dimensions for said membrane also only requires routine skill in the art.

16. Claims 2, 6, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '580 as applied to claim 1 above, and further in view of Yukawa et al (USP 6,059,946).

17. The references set forth all the limitations of these claims, but did not explicitly recite the use of a hydrophilic porous material. Yukawa discloses in an alternate electrochemical sensor the use of the hydrophilic material for the fluid transfer medium for the electrode (col. 4, lines 33-51). Hydrophilic material facilitates the wicking of fluid to the electrode thereby improving signal to noise and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Yukawa for the device of WO '580 and Mullen in order to improve electrode access to the fluid to be analyzed.

18. Claims 36-42, 51, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '580 and Mullen as applied to claim 1 above, and further in view of Zelin et al (USP 5,821,399).

19. With respect to claims 36-42, WO '580 and Mullen already disclosed the device of claim 1 (see rejection above). They did not explicitly recite that device being utilized in conjunction with a control means for controlling electrical input and output and with a software algorithm. Zelin teaches in an alternate blood analysis device that control systems are well known in the art. In particular, Zelin teaches a control means for controlling the electrical signals as well as software for calculating the concentration of biological sample. See col. 6, line 66 through col. 8, lines 32 and col. 12, lines 7-56. Such a control means provides a means for an unskilled

Art Unit: 1753

operator to utilize the device of WO '580 and Mullen without the aid of a skilled technician (col. 2, lines 21-39) and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Zelin for the the device of WO '580 and Mullen in order to provide a reliable automated blood analysis device.

20. With respect to claims 51 and 54 (those limitations not covered above), Zelin discloses using the device repeatedly (col. 7, lines 1-10). Repeated usage would require a plurality of device of WO '580 and Mullen.

*Allowable Subject Matter*

21. Absent double patenting issues, claims 19-30 are allowed.

22. Claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

23. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 3 and 4, the prior art does not disclose nor render obvious all the limitations of claim 2 and further comprising the specified proximal portion being more porous than the specified distal portion. With respect to claims 19-30, the prior art does not disclose nor render obvious all the limitations of claim 19 with particular attention to the specified combination of first, second, and porous material layer where the access openings, the layer of porous material and the first layer of conductive material provide the fluid transfer pathway.



*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (571) 272-1342.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for all official communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen  
Primary Examiner  
AU 1753  
January 12, 2004